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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,392	02/06/2001	Stefan G. Schreck	ECV-5620	4519

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EXAMINER
FERKO, KATHRYN P

ART UNIT	PAPER NUMBER
3743	11

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,392	SCHRECK ET AL.	
	Examiner	Art Unit	
	Kathryn Ferko	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6-8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 12a, 12b, 58a, 58b, 130a, 532b 556a, or 558c. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 126, 11a, 37a, 58, 22, 522b. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5-11, 20, 23-28, 30, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrari et al. in US Patent No. 6,190,357.

Ferrari et al. disclose a system for performing a surgical procedure within a blood vessel, having at least one guidewire (such as 27), the guidewire is

inserted into a body vessel, as recited in column 10, lines 40-67 and column 11; an antegrade probe (such as 42, etc.) having a distal portion, the antegrade probe having at least one antegrade guidewire lumen (such as 50, etc.), the antegrade guidewire lumen terminating in at least one guidewire port, the at least one guidewire port positioned radially about the antegrade distal portion substantially parallel to the longitudinal axis of the antegrade probe, as recited in column 2, lines 23-26, column 10, lines 40-67, column 11, column 14, lines 5-10 and seen in figures 1-9B; a retrograde probe (such as 42, etc.) having a distal portion, the retrograde probe having at least one retrograde guidewire lumen (such as 50, etc) the retrograde guidewire lumen terminating in at least one guidewire port, the at least one retrograde guidewire port positioned radially about the retrograde distal portion substantially parallel to the longitudinal axis of the retrograde probe and co-aligned with the antegrade probe, as recited in column 2, lines 23-26, column 10, lines 40-67, column 11, column 14, lines 5-10 and seen in figures 1-9B; at least one of the antegrade probe and the retrograde probe further comprising at least one lumen (such as 38, etc), as recited in column 4, lines 35-41, column 8, lines 15-23, and column 9, lines 1-13; an antegrade probe and retrograde probe that are placed over the guidewire so that the guidewire resides within the at least one antegrade guidewire port and the at least one retrograde guidewire port and wherein the at least one retrograde guidewire port is co-aligned with the at least one antegrade guidewire port, as seen in figures 1-9B, 18, 21, and 22; an antegrade probe and the retrograde

probe that are each engageable with one of the two pieces of tissue, to stabilize the tissue pieces, as recited in column 14, lines 5-10; an antegrade probe and retrograde probe that are mutually engageable with the two pieces of tissue to stabilize the tissue pieces interposed therebetween, as recited in column 14, lines 5-10; at least one lumen comprises a vacuum lumen, as recited in column 18, lines 55-60 and column 20, lines 36-46; at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of the antegrade probe, thereby enabling the grasping and manipulation of tissue, as recited in column 20, lines 36-46; at least one vacuum lumen that terminates in at least one vacuum port at the distal portion of the retrograde probe, thereby enabling the grasping and manipulation of tissue, as recited in column 20, lines 36-46; at least one of the distal portion of at least one of the antegrade probe and the retrograde probe that is substantially perpendicular to the longitudinal axis of the antegrade or retrograde probe, as recited in column 14, lines 5-10, wherein when inserted would be positioned as such; a distal portion of at least one the antegrade probe and the retrograde probe that is tapered, as seen in figure 22; at least one of the antegrade probe distal portion and the retrograde probe distal portion disposes at least one deployable alignment mechanism, as recited in column 20, lines 60-67 and column 21, lines 1-3; at least one of the antegrade probe and retrograde probe have sufficient length, steerability and maneuverability to reach the tissue from a peripheral insertion site; a peripheral insertion site is the femoral artery, as recited in column 5, lines 28-39; a

peripheral insertion site is the brachial artery, as recited in column 5, lines 28-39; a steering mechanism located proximate to the distal portion of at least one of the antegrade probe and the retrograde probe, as recited in column 19, lines 15-42; a steering conduit attached to the distal portion of at least one of the antegrade probe and the retrograde probe, the steering conduit in communication with an operator through one of the at least one antegrade lumen and the at least one retrograde lumen, as recited in column 19, lines 15-42; and at least one echogenic member at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization, as recited in column 21, lines 1-3.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3, 4, 12-19, 21, 22, 29, 31-35, and 38-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari et al. in US Patent No. 6,190,357.

Ferrari disclose the invention with the exception of explicitly reciting a second guidewire and wherein the antegrade probe comprises a first antegrade guidewire lumen terminating in a first antegrade guidewire port and a second antegrade guidewire lumen terminating in a second antegrade guidewire port and the retrograde probe comprises a first retrograde guidewire lumen terminating in

a first retrograde guidewire port and a second retrograde guidewire lumen terminating in a second retrograde guidewire port; a first guidewire that resides within the first antegrade guidewire lumen and the first retrograde guidewire lumen and the second guidewire resides in the second antegrade guidewire lumen and the second retrograde guidewire lumen to align the distal portion of the antegrade probe with the distal portion of the retrograde probe; at least one tissue fastener at the distal end of either the retrograde probe or the antegrade probe; a tissue fastener that is a suture-based tissue fastener; a tissue fastener that is a clip; a tissue fastener that is a staple; a tissue fastener receiver, the receiver providing cooperative stabilization of tissue while affixing the tissue fastener; at least one lumen comprises a tissue fastening lumen; at least two alignment arms flexibly attached to the distal portion of at least one of the antegrade probe and the retrograde probe; a deployment conduit operably connected to the at least two alignment arms; the deployment conduit attached to a deployment actuator; the at least two alignment arms having a retracted position wherein the arms are located proximal to the distal portion of at least one of the antegrade probe and the retrograde probe; the at least two alignment arms having a deployed position wherein the arms are extended radially from the distal portion of at least one of the antegrade probe and the retrograde probe; and the retracted and deployed positions achieved through manipulation of the deployment actuator; a polymer coating which can be wholly or selectively applied at or near the distal portion of one of the antegrade probe and the

retrograde probe to enhance echo visualization; or a method of stabilizing tissue, via delivering an antegrade probe to a position antegrade to the tissue; delivering a retrograde probe to a position retrograde to the tissue; aligning the first probe and the second probe longitudinally; using one or more of the first and the second probes to stabilize the tissue; and using one or more of the first and the second probes to fasten the tissue; all of the steps of the method are that completed without arresting the heart.

On the other hand, Ferrari et al., in column 9, lines 1-11 discuss that any number of lumens can be integrally formed in the tubular body, and in column 4, lines 35-41 state that the additional lumens can be for tool access. Therefore, it is within the scope of the invention and obvious to one with ordinary skill in the art to provide the system of Ferrari et al with a second guidewire, wherein the antegrade probe comprises a first antegrade guidewire lumen terminating in a first antegrade guidewire port and a second antegrade guidewire lumen terminating in a second antegrade guidewire port and the retrograde probe comprises a first retrograde guidewire lumen terminating in a first retrograde guidewire port and a second retrograde guidewire lumen terminating in a second retrograde guidewire port; a first guidewire that resides within the first antegrade guidewire lumen and the first retrograde guidewire lumen and the second guidewire resides in the second antegrade guidewire lumen and the second retrograde guidewire lumen to align the distal portion of the antegrade probe with the distal portion of the retrograde probe; at least one tissue fastener at the distal

end of either the retrograde probe or the antegrade probe; a tissue fastener that is a suture-based tissue fastener; a tissue fastener that is a clip; and a tissue fastener that is a staple (wherein the tissue fasteners are disclosed as equivalents in the current application). Further, it would be obvious when incorporating a tissue fastener to include a tissue fastener receiver for the purpose of providing cooperative stabilization of tissue while affixing the tissue fastener; at least two alignment arms flexibly attached to the distal portion of at least one of the antegrade probe and the retrograde probe; a deployment conduit operably connected to the at least two alignment arms; the deployment conduit attached to a deployment actuator; the at least two alignment arms having a retracted position wherein the arms are located proximal to the distal portion of at least one of the antegrade probe and the retrograde probe; the at least two alignment arms having a deployed position wherein the arms are extended radially from the distal portion of at least one of the antegrade probe and the retrograde probe; and the retracted and deployed positions achieved through manipulation of the deployment actuator, for the purpose of achieving tissue fixation. Moreover, a polymer coating which can be wholly or selectively applied at or near the distal portion of one of the antegrade probe and the retrograde probe to enhance echo visualization would also be obvious to one with ordinary skill in the art. Additionally, when modifying the invention to incorporate tissue fixation means the method of stabilizing tissue as claimed would occur, and thus be obvious.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2003/0130571; US 2002/0049402; US Patent No. 6,582,388; US Patent No. 6,508,777; US Patent No. 6,443,922; US Patent No. 6,234,995; and US Patent No. 6,010,531.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
July 29, 2003

Henry Bennett
Supervisory Patent Examiner
Group 3700